

- 3) claims 1, 3, 4, and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5, 516, 925 (hereinafter "Pedersen");
and
- 4) claims 3, 7, 8, 10, 14, and 16 were rejected under 35 U.S.C. 103(a)
as being obvious over Pedersen.

I. REJECTIONS UNDER 35 U.S.C. 102(b)

A. *Henry*

Claims 1-3, 12, 13, 17, 23, and 26-28 were rejected under 35 U.S.C. 102(b) as being anticipated by Henry. Independent claims 1 and 17 have been amended to include the subject matter of claims 4 and 21, respectively, which were not rejected under 35 U.S.C. 102(b). Therefore, this rejection is believed to have been rendered moot. Reconsideration is respectfully requested.

B. *Pedersen*

Claims 1, 3, 4, and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen. The Examiner has cited column 11, Example 8, in making this rejection. However, an important distinction between the amended claim 1 of the present application and Example 8 of Pedersen appears to have been overlooked. The method described in claim 1 is for enhancing solubility of an amino acid chelate by an admixing step, not a method of reacting an organic acid with an amino acid chelate. The composition of the amino acid chelate molecule does not substantially change upon introducing the organic acid solubilizing agent. Conversely, Example 8 of Pedersen reacts malic acid with an iron amino acid chelate/complex to form a new product. The language of "enhancing solubility" by a step of "admixing" makes this

distinction clear in the claim language of the present application. As Pedersen does not read on this aspect of claim 1, reconsideration is respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. 103(a)

A. *Henry*

Claims 4-9, 11, 14-16, 18-22, 24, and 25 were rejected under 35 U.S.C. 103(a) as being obvious over Henry. Claim 1 and 17 were amended to include the subject matter of claims 4 and 21, respectively. Thus, a response to the obviousness rejections will be discussed with respect to amended claims 1 and 17. If newly amended claims 1 and 17 are found to be allowable, all claims that depend therefrom will also be in allowable condition.

The Examiner has asserted that a solubilizing agent to iron content weight ratio of 5:1 to 1:1 (as filed in claim 4, now in claim 1) is obvious in view of Henry. Henry discloses various compositions including color stable iron fortified drink mixes, ready-to-drink beverages, and foods other than beverages that can contain zinc. Examples of iron fortificants that can be used include ferrous salts, iron chelates, and iron-sugar-carboxylate complexes. Additionally, many other ingredients can be present, including a zinc source, vitamins and minerals, coloring agent, flavoring agent, acid component, sweetener, clouding/thickening agent, antioxidant, and complexing/reducing agents.

In examining the application, relatively broad ranges of acid content and USRDI iron content can be present. However, as many different types of iron sources can be used, a specific look at the embodiments where an amino acid chelate and an organic acid are present provides a better understanding of what the Henry reference actually teaches and enables. To illustrate, Example 3 includes a composition

including 0.3 wt% Ferrochel and 12.6 wt% citric acid. Ferrochel is a tradename for an iron amino amino acid chelate comprising 2 glycine ligands coordinated with a single iron atom. With this information, the iron content of the Ferrochel can be calculated to be about 0.08 wt% of the total composition (based on molecular weights of about 75.07 for each glycine, and 55.85 for iron). Thus, the ratio of citric acid (12.6 wt%) to iron content (0.08 wt%) is about 157:1. This is well outside of the range provided by amended claims 1 and 17. Similar calculations can be done for each of the other Examples where an iron amino acid chelate and organic acid is present. Such calculations underscore the fact that none of the Examples show an amino acid chelate and an organic acid in a single composition having a ratio that is even close to the solubilizing agent to iron content ratios required by claims 1 and 17. Further, there is no teaching or suggestion in Henry that organic acid is added to provide enhancement of solubility of an amino acid chelate. Acid is added to lower the pH, or to prevent off-color development. As such, reconsideration of this rejection is respectfully requested.

B. Pedersen

Claims 3, 7, 8, 10, 14, and 16 were rejected under 35 U.S.C. 103(a) as being obvious over Pedersen. Specifically, the Examiner points to column 11, Example 8, of Pedersen in making this rejection. Example 8 describes an iron(III) lysyl glycerophosphate stabilized with malic acid. Specifically, malic acid is added to a filtrate that includes iron (III) that is chelated to lysine and complexed with a glycerophosphate. Upon addition of the malic acid, the malic acid complexes with the iron (III). Example 8 itself states that an "iron (III) lysyl glycerophosphate/malate" is formed.

Conversely, as mentioned previously, claim 1 provides a method of enhancing the solubility of an amino acid chelate by an admixing step, not a method of reacting an organic acid with an amino acid chelate to form a new complex. For example, Ferrochel, as described with respect to the Henry reference, is an amino acid chelate that includes ferrous iron and two glycine ligands chelated to the iron. Upon admixing an organic acid, such as malic acid, with Ferrochel at the ratios claimed, reaction between the iron and the organic acid will substantially not occur. However, the presence of the organic acid at the claimed ratios improves the solubility of the iron amino acid composition. This is a significant distinction between the method step of admixing of the present claims, and the step of reacting as exemplified in Pedersen. Therefore, reconsideration of this rejection is respectfully requested.

Applicants submit that each and every amendment herein, and throughout the prosecution of the present application is fully supported by the specification as originally filed, and that no new matter has been added.

In view of the foregoing, Applicants believe that claims 1-3, 5-20, and 22-28 present allowable subject matter, and allowance is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be alleviated during a telephone interview, the Examiner is invited to telephone Gary Oakeson, or the undersigned attorney, at (801) 566-6633, so that such issues may be resolved as expeditiously as possible.

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Please charge any additional fees, except for Issue Fee, or credit any
overpayment to Deposit Account No. 20-0100.

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Respectfully submitted,

q/h

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AMENDMENT (marked-up version of claims)

Please amend claim 1 as follows:

1. (Amended) A method of enhancing the solubility of iron amino acid chelates and iron proteinates comprising admixing an effective amount of an organic acid solubilizing agent with an iron amino acid chelate or iron proteinate having a ligand to metal molar ratio from about 1:1 to 4:1, wherein the solubilizing agent to iron content weight ratio is from about 5:1 to 1:1.

Please cancel claim 4.

Please amend claim 17 as follows:

17. (Amended) A method of enhancing the solubility of an iron amino acid chelate- or iron proteinate-sugar complex comprising admixing an effective amount of an organic acid solubilizing agent into said iron amino acid chelate- or iron proteinate-sugar complex, wherein the solubilizing agent to iron content ratio is from about 4:1 to 1:1 by weight.

Please cancel claim 21.